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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,807	02/20/2004	Tetsuo Shibuya	JP920030020US1	7767

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William E. Lewis  
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EXAMINER
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SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/783,807	<b>Applicant(s)</b> SHIBUYA, TETSUO	
	<b>Examiner</b> Carolyn Smith	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2008 and 10 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 10-12, 15, 16, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-9, 13-14, 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 12/09/08 and 11/10/08, have been entered.

Amended claims 1-3, 8-9, 13-14, and 17, filed 11/10/08, are acknowledged. Claims 4-7, 10-12, 15-16, and 18-19 remain withdrawn due to being drawn to non-elected Groups.

Claims herein under examination are 1-3, 8-9, 13-14, and 17.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 8-9, and 13-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-3 recites a "system" containing various units. Giving the claims a broad reasonable interpretation, these limitations are broad enough to encompass a software system with software components. Claims 1-3 is therefore held as software per se.

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Claims 8-9 and 13-14 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

The claimed subject matter is not limited to a particular apparatus or machine. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter (In re Grams 12 USPQ2d 1824 Fed. Cir. 1989). Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. Applicant is cautioned against introduction of new matter in an amendment.

***Claim Rejections - 35 USC § 112, Second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that claims 1-3 recite “unit for” limitations. It is noted that some of the limitations in claim 1-3 invoke 35 USC 112, 6th paragraph, whereas others do not. Therefore, it

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is unclear if Applicant is intending to invoke 35 USC 112, 6th paragraph, for claims 1-3.

Clarification of this issue is requested.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8-9, 13-14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujimiya et al. (P/N 5,706,498) in view of Myers et al. (US 6,714,874 B1).

Fujimiya et al. describe a computer system, method, program, and computer readable medium for executable screening nucleotide sequences (abstract and Figures 2-4, col. 3, second and third paragraphs, col. 8, first 2 paragraphs; and col. 13, first paragraph), as stated in the preamble of instant claims 1, 8, 13, and 17. Fujimiya et al. describe storing sequence data of genes including target sequence data and key sequence data which exhibit a high degree of similarity (abstract and title and Figure 2 and col. 1, third paragraph; col. 2, fourth paragraph; col. 9, last paragraph) for homology retrieval (col. 2, fourth paragraph) including key memory and target memory (Figure 2) which represent a target and a complementary sequence data storing units, as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. describe retrieval databases and preparing a gene probe and analyzing and determining the final sequence of bases by extracting a portion of the gene probe bound to a chromosome (col. 2, second and third

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paragraph) which represents generating complementary sequence data from a probe sequence and storing such data, as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. describe a dynamic operation unit for determining the degree of similarity between the target data and the key data by utilizing base sequence data of each (abstract), grouping homologous sequences, and retrieving the homologous gene sequence (col. 1, fifth paragraph and col. 2, second paragraph) using dynamic programming by summing up points from the starting point of the operation for determining the locally optimal path (i.e. number of adjustments) solution as a whole using insertions, deletions, and substitutions for the first to last combinations of data (col. 2, last paragraph, col. 3, third and fourth paragraphs, and Figures 7a and 7b), altering target data one after another with respect to key data and determining degree of similarity by entering the base sequence data one after another of the target data and storing the sum value of for the sequence data and maximal sum value occurring at the time of operation, classifying the maximal sum values, and determining the order of the sequence data as an object of extraction (col. 9, lines 21-67; col. 12, lines 32-39; col. 13, lines 1-22), as well as displaying maximal values of each target data in the order of higher degrees of similarity (col. 23, third paragraph), and computation amounting to the number of steps of the basic operations, based on bases in agreement or being replaced (col. 6, third paragraph), and probe binding evaluation (col. 2, second and third paragraphs) which represents an evaluation processing unit for evaluating a binding possibility of the target nucleotide sequence data to the probe sequence via determination of whether the complementary sequence data is similar to a subsequence of the target nucleotide sequence data in descending order of edit distance of binding precision, wherein edit distance is the number of times nucleotides of the subsequence are required to be adjusted to generate the complementary

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(key) sequence data. Fujimiya et al. describe preparing a gene probe on the basis of the gene having high retrieval accuracy and analyzing and determining the binding possibility of the probe on the involved gene on a chromosome (col. 2, second and third paragraphs), as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. describe a database and retrieving of sequence data using a sequence similar thereto (col. 1, first paragraph) and probe binding analysis and determination (col. 2, second and third paragraphs) and evaluation processing for a user (col. 23, third paragraph) which represents a storage unit for storing the evaluation result for the user in determining probe binding effectiveness and reliability, as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. describe using 10 base elements in the sequence data (col. 4, second paragraph) as well as using partial sequences (col. 4, third paragraph). Fujimiya et al. describe a system including storage of data and a similarity degree whereby the score value at the initial condition is set to zero given the condition in which the maximal length  $\alpha$  of the sequence is inserted or lost at one time involving partial sequences as well as setting  $\alpha$  to 1 to get a maximal score value (col. 4, last paragraph, and col. 5, and abstract) and performing an operation until reaching a predetermined length of the key or target data and acquiring the maximal value of the sum values with direction selection data (col. 10, line 57 to col. 11, line 43) as well as a constant value to compare sum values (col. 12, lines 1-17) which represents a maximum edit distance storing unit, as stated in instant claims 2, 8, 13, and 17. Fujimiya et al. describe setting a maximal value as a score of the node and applied to the origin and subsequent lattice points until finishing the basic operation and determining the wholly optimal disposition of the three routes (col. 5, last paragraph to col. 6, second paragraph) which represents determining a termination point and a termination-determining unit determining evaluation carried out over maximal

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(acceptable) edit distance, as stated in instant claims 3, 9, and 14. Fujimiya et al. describe a score value of each route is added, including target-side data and key-side data, as well as outputting sequence data and displaying maximal values and direction selection data (path) (col. 3, third to col. 4, first paragraph; col. 5, second to last paragraph to col. 6, second paragraph; col. 10; col. 11, lines 44-48; col. 20, first paragraph; col. 23, third paragraph; and Figures 7 and 8) which represents reading out each target nucleotide sequence data, complementary sequence data, and each maximum acceptable edit distance, as stated in instant claims 8, 13, and 17. Fujimiya et al. describe the wholly optimal disposition is determined after the basic operations have been made (col. 6, second paragraph and Figures 3-4 and 6) and an interruption signal issued to the microprocessor when the operation is terminated (col. 24, last paragraph) which represents generating a termination signal in response to the determination result, as stated in instant claims 9 and 14. Fujimiya et al. describe using the ability to apply dynamic programming to a local region having approximately 16 bases (col. 7, fourth paragraph). Fujimiya et al. do not describe evaluation is performed in descending order from a first (maximum) edit distance value to a second edit distance value, the second edit distance value being lower than the first (maximum) edit distance value.

Myers et al. describe determining the genomic sequence and screening fragments with their complementary sequences (abstract; col. 2, lines 45-54), identifying a high edit score, inserting a column at the left border of the region, sweeping region from left to right and moving bases leftward if such a move decreases the edit score, repeating the sweeping from right to left, comparing alignments produced in both sweeps and keeping the alignment with the lowest edit score (claim 12; col. 23, 6<sup>th</sup> paragraph to col. 24, 3rd paragraph) which represents an evaluation



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is performed in descending order from a first (maximum) edit distance value to a second edit distance value, the second edit distance value being lower than the first (maximum) edit distance value.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to correct alignment within a region as taught by Myers et al. in the screening method of Fujimiya et al. wherein the motivation would have been to assess sequences with an insertion or deficiency of a sequence portion taken into account in a manner that reduces the enormous volume of computation required with dynamic programming, as stated by Fujimiya et al. (col. 2, fifth and sixth paragraphs). One of ordinary skill in the art would have expected success since Fujimiya et al. and Myers et al. both use dynamic programming.

Thus, Fujimiya et al. in view of Myers et al. make obvious the instant invention.

Applicant summarizes MPEP requirements for a 35 USC 102 rejection. Applicant summarizes Fujimiya et al. Applicant argues that Fujimiya et al. fail to teach evaluating a binding possibility as recited in the claims in accordance with an edit distance. This statement is found unpersuasive as Fujimiya et al. describe a database and retrieving of sequence data using a sequence similar thereto (col. 1, first paragraph) and probe binding analysis and determination (col. 2, second and third paragraphs) and evaluation processing for a user (col. 23, third paragraph). In addition, Fujimiya et al. describe a dynamic operation unit for determining the degree of similarity between the target data and the key data by utilizing base sequence data of each (abstract), grouping homologous sequences, and retrieving the homologous gene sequence (col. 1, fifth paragraph and col. 2, second paragraph) using dynamic programming by summing

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up points from the starting point of the operation for determining the locally optimal path (i.e. number of adjustments) solution as a whole using insertions, deletions, and substitutions for the first to last combinations of data (col. 2, last paragraph, col. 3, third and fourth paragraphs, and Figures 7a and 7b), altering target data one after another with respect to key data and determining degree of similarity by entering the base sequence data one after another of the target data and storing the sum value of for the sequence data and maximal sum value occurring at the time of operation, classifying the maximal sum values, and determining the order of the sequence data as an object of extraction (col. 9, lines 21-67; col. 12, lines 32-39; col. 13, lines 1-22). Applicant argues that the scoring of Fujimiya et al. is related to insertions, deletions, and substitutions, but the system of adding and subtracting does not anticipate the recited edit distance. This statement is found unpersuasive the limitation of evaluation processing being performed in descending order from a first (maximum) edit distance value to a second edit distance value, the second edit distance value being lower than the first (maximum) edit distance value as now recited in the instant claims is taught by Myers et al. who describe determining the genomic sequence and screening fragments with their complementary sequences (abstract; col. 2, lines 45-54), identifying a high edit score, inserting a column at the left border of the region, sweeping region from left to right and moving bases leftward if such a move decreases the edit score, repeating the sweeping from right to left, comparing alignments produced in both sweeps and keeping the alignment with the lowest edit score (claim 12; col. 23, 6<sup>th</sup> paragraph to col. 24, 3rd paragraph). Applicant argues Fujimiya et al. do not teaching binding effectiveness and reliability of the probe to the target. This statement is found unpersuasive as Fujimiya et al. describe a database and retrieving of sequence data using a sequence similar thereto (col. 1, first

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paragraph) and probe binding analysis and determination (col. 2, second and third paragraphs) and evaluation processing for a user (col. 23, third paragraph). It is also noted that determining similarity reasonably encompasses determining effectiveness and reliability of a probe to a target. Applicant states that the instant claims have been amended and that Fujimiya et al. do not anticipate these new limitations. It is noted that Myers et al. describe the amended limitations. Applicant's arguments are deemed unpersuasive for the reasons given above.

### ***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

February 18, 2009

/Carolyn Smith/  
Primary Examiner  
AU 1631